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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,935	05/03/1999	MINORU TAKEBE	211A-2828-PC	3005

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KODA & ANDROLIA
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SUITE 1430
LOS ANGELES, CA 90067-3024

EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/02/2003

38

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/284,935

Applicant(s)

TAKEBE ET AL.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,2,5,7 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,2,5,7 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/284,935 has been entered.

Status of claims

Claims 1, 2, 5, 7 and 9-11 as amended (Paper No. 29 filed 7/09/2003) are pending and under examination.

Applicants in the Paper No. 29 filed 7/09/2003 canceled claim 4.

Applicants in the Paper No. 13 filed 4/17/2001 canceled claims 3, 6 and 8.

Claim Rejections - 35 U.S.C. § 112

Indefinite

Claims 1, 2, 5, 7 and 9-11 remain/are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2 and 5 are indefinite with respect to the phrase "a substance that remains undigested ...". This "substance" is required to be present in the claimed product or in "material" obtained by the claimed method. However, applicants do not specify the nature of this substance. The method as claimed does not require possession or recovery of the intended "substance".

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According to the generic disclosure, the claimed undigested “substance” appears to be “enzyme undecomposed substance” (see specification page 7, line 1). Thus, in the instant office action the claimed “substance” is interpreted as some substance that could be present in the material produced by koji fungal culture enzymatic fermentation of grains.

Claims 1, 2 and 5 are indefinite with respect to the phrase “decomposing a predetermined amount of phytic acid”. Neither claimed invention nor specification indicates how much is “a predetermined amount of phytic acid”. Neither claimed invention nor specification indicates what considerations are relied upon to establish an exact “predetermined amount of phytic acid” to be decomposed upon completion of the process. Thus, the meaning of the phrase “decomposing a predetermined amount of phytic acid” is interpreted as a natural process of the phytic acid removal (decomposition) during fermentation and/or hydrolysis of grains by koji fungal cultures.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37CFR 3.73(b).

1. Claims 5, 7 and 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,517,831 [G].

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are directed to a process for preparing a product containing a “health-promoting component” or a “substance” wherein the process is a process for fermentation and hydrolysis of crops or grains by koji fungal cultures in the presence of the additional beneficial microorganisms including beneficial lactic bacteria.

The process of the claimed invention of US 6,517,831 requires the combined use of two groups of microorganisms including koji mold (fungal culture) and lactic bacteria (see claim 3) for completion of the fermentation and hydrolysis process. The material under fermentation and hydrolysis is derived from crops (see claims) or soybeans (see disclosure, col.1, lines 14-16).

The instant invention is drawn to a fermentation process wherein the process encompasses the combined use of two groups of microorganisms including koji mold (fungal culture) and beneficial microorganisms that are the lactic bacteria (see claim 7). The material

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under fermentation and hydrolysis is derived from grains (see claims) or soybeans (see page 1 or 11 of specification).

Therefore, the claimed processes are substantially similar.

Although the claimed invention of US 6,517,831 is silent with regard to “decomposing a predetermined amount of phytic acid” as required by the instant claims, the removal of phytic acid is regarded as a natural process during the koji mold fermentation and/or hydrolysis of the materials including crops, grains or soybeans. Moreover, the completion of the claimed process of US 6,517,831 encompasses the removal of phytic acid from the final product in the light of the specification, for example: see col. 13, lines 20-25 or lines 61-63; see at col. 14, table 6 or lines 38-41. Thus, the process of US 6,517,831 includes the removal or decomposing of some predetermined amount of phytic acid to the same extend as it is required by the instant claims.

Although some of the claims of US 6,517,831 indicate that “a health-promoting component” is obtained in a manner “so as to be absorbed by digestive tract” (claims 5 and 7-9), the process of US 6,517,831 does not exclude obtaining of some “substance that remains undigested and unabsorbed in small intestines”. Moreover, some substance or component that “remains indigested and unabsorbed in small intestines” as required by the instant claims could be digested and/or absorbed further down in the digestive tract. Both processes result in obtaining of some complex fermented material of unspecified contents wherein the complex fermented material is reasonably expected to include components that can be “absorbed by digestive tract” and substances that can remain “undigested and unabsorbed in small intestines”. The meaning of the limitations drawn to the nature of materials obtained as result of the claimed processes is overlapping.

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Some of the instant claims require addition of water in amount “until a content of said water is 50% by weight” which means addition of equal weigh amount to the preexisting weight amount. The claimed invention of US 6,517,831 encompasses addition of at least some amounts of water (see claim 1). The added water amounts are the same as presently claimed in the light of the specification of US 6,517,831, for example: see col. 12, line 30, wherein the specification of US 6,517,831 discloses addition of water in equal weight amount to the preexisting weight amount.

Accordingly, the presently claimed process and the process of US 6,517,831 are obvious variants. Thus, the inventions as claimed are co-extensive.

2. Claims 1 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,303,161 [D].

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are directed to a product containing a “health-promoting component” or a “substance” wherein the product is obtained by the process for fermentation and hydrolysis of crops or grains by koji fungal cultures in the presence of additional beneficial microorganisms including beneficial lactic bacteria.

The focus of the claimed invention of US 6,303,161 is on the combination of two groups of microorganisms including koji mold (fungal culture) and lactic bacteria (see claim 3) which are combined to complete the fermentation process. Thus, the claimed product obtained by the process of US 6,303,161 consists of koji molds, beneficial lactic bacteria and some materials

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fermented by two groups of microorganisms. The fermented material is derived from crops (see claims) or soybeans (see col. 1, line 11).

The instant invention is drawn to a product obtained by fermentation process wherein the process encompasses the combined use of two groups of microorganisms including koji mold (fungal culture) and beneficial microorganisms that are lactic bacteria in the light of claim 7. Thus, the claimed product obtained by the method of instant invention comprises koji molds, lactic bacteria and some materials fermented by two groups of microorganisms. The fermented material is derived from grains (see claims) or soybeans (see specification page 1).

Thus, the claimed products obtained by processes are substantially similar.

Although the claimed invention of US 6,303,161 is silent with regard to “decomposing a predetermined amount of phytic acid” as required by the instant claims, the removal of phytic acid is regarded as a natural process during the koji mold fermentation and/or hydrolysis of the materials including crops, grains or soybeans. Moreover, the completion of the claimed process of US 6,303,161 encompasses the removal of phytic acid from the final product in the light of the specification, for example: see col. 12, lines 50-52 or see at col. 3, line 19 or table 6 or lines 62-64. Therefore, the product obtained by the process of US 6,303, 161 does not contain phytic acid to the same extend as it is required by the instant claims.

Although some of the claims of US 6,303,161 indicate that “a health-promoting component” is obtained in a manner “so as to be absorbed by digestive tract” (claims 5 and 7-9), the product or “component” obtained by the process of US 6,303,161 does not exclude “substance that remains undigested and unabsorbed in small intestines”. Moreover, some substance or component that “remains indigested and unabsorbed in small intestines” as required

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by the instant claims could be digested and/or absorbed further down in the digestive tract as encompassed by US 6,303,161. The meaning of the limitations drawn to the nature of materials obtained as result of the claimed processes is overlapping. Thus, both products being complex fermented materials are reasonably expected to include both components that can be “absorbed by digestive tract” and substances that can remain “undigested and unabsorbed in small intestines”.

Some of the instant claims require addition of water in amount “until a content of said water is 50% by weight” which means addition of equal weigh amount to the preexisting weight amount. The claimed invention of US 6,303,161 encompasses addition of at least some amounts of water that are reasonably expected to be mandatory for microbial growth and enzymatic fermentation and hydrolysis. Moreover, the added water amounts are the same as presently claimed in the light of the specification of US 6,303, 161, for example: see col. 14, line 25 wherein the specification of US 6,303,161 discloses addition of water in equal weight amount to the preexisting weight amount.

Accordingly, the presently claimed product and the product of US 6,303,161 are obvious variants. Thus, the inventions as claimed are co-extensive.

3. Claims 2 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,303,161 in view of WO 96/08261.

Although the claims of US 6,303,161 are not identical to the instant claims 2 and 9, the claimed inventions not patentably distinct from each other because the conflicting claims are

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directed to a product containing a “health-promoting component” or a “substance” wherein the product is obtained by the process for fermentation and hydrolysis of crops or grains by koji fungal cultures in the presence of additional beneficial microorganisms including beneficial lactic bacteria for the reasons as explained above. Both final products incorporate koji molds, beneficial lactic bacteria and fermented materials as explained above.

However, the presently claimed product is mixed with additional starch or with “resistant” starch (see claim 2) after being obtained by presently claimed process. It is noted herein that the instant specification does not provide particular definitions about the term “resistant starch”.

The claimed product of US 6,303,161 does not appear to incorporate additional starch from an outside source but it contains at least some starch in the final fermented product (table 10 or 12). Therefore, in the lack of definitions about “resistant starch” as intended by applicant, the presently claimed product and the product of US 6,303,161 are obvious variants because they both incorporate some starch. Thus, the final contents of the claimed products are substantially similar.

In alternative, if the starch in the product of US 6,303,161 is not additional “resistant” starch, it would be obvious to one of ordinary skill in the art to add “resistant starch” to the health promoting component containing product of US 6,303,161 in order to obtain the presently claimed beneficial microorganism propagation-promoting material in view of the teaching by WO96/08261.

The cited WO 96/08261 teaches that resistant starch is a suitable carrier for beneficial microorganisms including lactic bacteria and that resistant starch acts as a growth-promoting

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medium for beneficial microorganisms including lactic bacteria in the large bowel of the gastrointestinal tract (see abstract or page 3). WO 96/08261 teaches addition of resistant starch to the products with probiotics including lactic bacteria. Thus, one of skill in the art would have been motivated to add resistant starch to the products with beneficial microorganisms for the expected benefits provided by probiotics including lactic bacteria in the gastrointestinal tract particularly in large bowel as taught by WO 96/08621 (page 1, lines 25-30).

Accordingly, the presently claimed product and the product of US 6,303,161 are considered to be obvious variants.

Thus, the inventions as claimed are co-extensive.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 5, 7, 9 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,885,632 [B].

Claims are directed to a process and a material-obtained-by-the process wherein the process encompasses steps of cooking grains, cooling grains, inoculating the grains with koji molds, adding water, cultivating the koji molds with pre-existing or added beneficial microorganisms and decomposing phytic acid. The claimed beneficial microorganisms are representatives of *Eumycetes* which are fungal cultures including koji molds. The intended effects of the claimed material are health-sustaining effects related to propagation of beneficial microorganisms on the material. The claimed fermented product comprises "a substance that

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remains undigested and unabsorbed in small intestines". Some claims are further drawn to adding water in amounts to reach the water content of 50% by weigh.

5,885,632 [B] teaches a process and a material-obtained-by-the process wherein the process encompasses steps of inoculating grains or crops such as soybeans with koji mold to create a koji preparation resultant, adding water to the resultant and removing phytic acid (see fig. 1; col. 4, lines 35-45 and lines 52-57) wherein that additional beneficial microorganisms contained (pre-existing) in the resultant are also koji mold preparations, for example: col. 6, lines 43-45. The phytic acid is decomposed in the method of US'632 to some "predetermined" amount within the meaning of the instant claims (col. 9, lines 34-37 and table 4). The effects of the US'632 product are health-promoting effects related to propagation of beneficial microorganisms and/or other health-promoting effects such as carcinopreventive (see abstract). The amount of water which is added and/or present during hydrolysis is at least 40% by weight and more (col. 6, line 25) as required by the presently claimed invention.

With respect to claim 7 it is noted that the taxonomic group of *Eumycetes* comprises all fungi including yeasts and koji molds belonging to *Aspergillus* (see Ainsworth & Bibsy's Dictionary of the Fungi at page 158). Thus, regardless the fact that some other microbial species might be intended, the method of the cited patent US'632 utilizes the same microorganisms as the claimed invention including representatives of *Eumycetes* that are koji molds or *Aspergillus*.

Thus, the fermentation and hydrolysis process as disclosed by US'632 is identical to the claimed process because both processes comprise identical active steps and identical materials. Therefore, the final fermented and hydrolyzed products are identical because they are obtained by identical methods. Although the cited US'632 is silent with regard to the "substance that remains undigested ...", this substance is inherently present in the final fermented/hydrolyzed product of US'632 because the US'632 protocol of making is identical to the presently claimed

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invention, particularly in view that the nature of this “substance” is not specified by the instant application and claims.

Therefore, US 5,885,632 anticipates the claimed invention.

Claims 1, 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,308,284 [A] in the light of evidence provided by teaching of US 5,885,632 [B].

Claims are directed to a process and a material-obtained-by-the process wherein the process encompasses steps of cooking grains, cooling grains, inoculating the grains with koji molds, adding water, cultivating the koji molds with pre-existing or added beneficial microorganisms and decomposing phytic acid. The claimed beneficial microorganisms are representatives of *Eumycetes* (yeasts) and lactic bacteria. The intended effects of the claimed material are health-sustaining effects related to propagation of beneficial microorganisms on the material. The claimed fermented product comprises “a substance that remains undigested and unabsorbed in small intestines”.

US 4,308,284 [A] teaches a process and a product obtained by the process comprising steps of cooking and cooling grains or soybeans, inoculating the grains with koji mold belonging to *Aspergillus*, adding aqueous suspension with two additional groups of beneficial microorganisms including yeasts *Saccharomyces* and lactic bacteria *Rediococcus*, fermenting and hydrolyzing the grains with three types of microorganisms including koji molds, yeasts and lactic bacteria. See disclosure at col. 7, lines 5-25.

The step of removing phytic acid which is contained in the grains or hydrolyzed resultant is inherently present in the method/composition-obtained-by-method of the cited patent '284 in the light of evidence as taught by US 5,885,632 [B]. For example: the teaching of US 5,885,632 [B] demonstrates that koji molds have high phytase which are enzymes decomposing phytic acid and that phytic acid is removed in the presence of added water during koji mold hydrolysis (see

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US'632 col. 9, lines 15 and col.8, lines 60-67). The cited US'284 encompasses the use of identical koji molds, the use of identical grains/resultants and the use of additional water at least in a form of aqueous suspension. Therefore, the event or the step of decomposing some amounts of phytic acid appears to be naturally or inherently present in the method and composition-obtained-by-methods disclosed by US'284. Thus, the disclosure of US 4,308,284 appears to anticipate the presently claimed invention because it encompasses identical components and identical steps as presently claimed. Although the cited US'284 is silent with regard to the "substance that remains undigested ...", this substance is inherently present in the US'284 final complex fermented and hydrolyzed product obtained by the process identical to the claimed process, particularly in view that the nature of this "substance" is not specified by the instant application and claims. The beneficial microorganisms are propagated on the fermented grains as disclosed by US'284 and thus, the effects that are intended by the instant claims and related to obtaining making material for promoting growth of beneficial microorganisms, appear to be achieved by the protocol as disclosed by US'284.

Therefore, US 4,308,284 anticipates the claimed invention.

Claim rejection over US 5,965,178 [E] in the light of evidence provided by US 5,885,632 [B] has been withdrawn. Although the method of making of US'178 encompasses grain fermentation with koji molds and lactic bacteria, the final product obtained is sake. Thus, due to the presence of the alcohol in the product obtained by process US'178 the koji molds and lactic bacteria would not be expected to propagate in the product obtained by method of US'178 and the material obtained could not be considered being a microorganism propagation promoting material encompassed by the presently claimed invention.

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Claim rejection under 35 U.S.C. 102(b) as being anticipated by US 4,329,370 [F] has been withdrawn. The method of US'370 drawn to the use of one group of microorganisms such as koji molds for fermentation and hydrolysis of grains. Drying in the method of US'370 inhibits the second group of pres-existing or contaminating bacteria.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 7, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,885,632 [B] and US 4,308,284 [A] and US 4,329,370 [F].

Claims are directed to a process and a material-obtained-by-the process wherein the process encompasses steps of cooking grains, inoculating grains with koji molds, adding water, cultivating the koji molds with beneficial microorganisms and decomposing phytic acid. The intended effects of the claimed material are health-sustaining effects related to propagation of beneficial microorganisms on the material. Some claims are further drawn to the use of beneficial microorganisms such as yeasts belonging to *Eumycetes* and lactic bacteria or bifidobacteria. Some claims are further drawn to the use of water content such as about 50%.

The cited patent US 5,885,632 is relied upon for the disclosure of a product and a product obtained by process wherein the process encompasses fermentation and hydrolysis of grains with one group of microorganisms such as koji molds and wherein the process encompasses addition of water to reach at least 40 % weight amount.

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The cited patent US 4,308,284 is relied upon for the disclosure of a product and a product obtained by process wherein the process encompasses fermentation and hydrolysis of grains with three groups of microorganisms including koji molds, yeasts and lactic bacteria. The process encompasses addition of some water but the cited patent is silent with particular amount of water added.

However, US 4,329,370 teaches that koji molds fermentations generally requires about 40-50% of water (col. 2, lines 61-62) and that reduction of water content would reduce amount of additional and/or contaminating bacteria (col. 2, lines 25-35).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was to adjust amounts of water to 50 % during fermentation and hydrolysis of grains by koji molds with a reasonable expectation in success in obtaining koji mold fermented materials because these amounts are generally used in koji fermentation of grains as clearly taught by US 5,965,178 and/or suggested by US 5,885,632. One of skill in the art would have been motivated to add water to the materials under fermentation by several groups of microbes as in the method of US 4,308,284 so as to reach amounts of 50 % or no less than 40% in order to avoid inhibition of additional bacteria as clearly taught by US 5,965,178. The reduction of water content would reduce viability of additional bacteria and, thus, fermentations that require viability of several groups of microorganisms including koji molds and bacteria are reasonably expected to need addition of 50 % of water as it is encompassed by the presently claimed invention. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Claims 1, 2, 5, 7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,885,632 [B] and US 4,308,284 [A] and US 4,329,370 [F] as applied to claims 1, 5, 7, 9 and 11 above, and further in view of WO 96/08261 [P].

Claims 1, 5, 7, 9 and 11 as explained above. Some claims are further drawn to incorporation of resistant starch into the product obtained by the claimed process.

The cited documents US 5,885,632 [B], US 4,308,284 [A] and US 4,329,370 [F] are relied upon as explained above. They are lacking disclosure related to incorporation of resistant starch into the product obtained by the claimed process.

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However, the cited WO 96/08261 teaches that resistant starch is a suitable carrier for beneficial microorganisms including lactic bacteria and that resistant starch acts as a growth-promoting medium for beneficial microorganisms including lactic bacteria in the large bowel of the gastrointestinal tract (see abstract or page 3). WO 96/08261 teaches addition of resistant starch to the beneficial health promoting products intended to provide for grow and propagation of probiotics including lactic bacteria.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was to add resistant starch to the products intended for propagation and growth of beneficial bacteria with a reasonable expectation in success in obtaining beneficial probiotic compositions as adequately taught by WO 96/08261. One of skill in the art would have been motivated to add resistant starch to the products with beneficial microorganisms for the expected health related beneficial effects provided by probiotics including lactic bacteria in the gastrointestinal tract particularly in large bowel as taught by WO 96/08621 (page 1, lines 25-30). Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Claims rejection under 35 U.S.C. § 103 over the prior art documents Remington [U], Merck [V], US 5,118,626 [C], JP 7-23725 [N] and JP 3-19686 [O] have been withdrawn due to redundancy of the teachings of these references.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

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September 29, 2003.

VERA AFREMOVA

PATENT EXAMINER

A handwritten signature in cursive script, appearing to read 'V. Afremova', followed by a long horizontal flourish line extending to the right.